UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,382	09/09/2004	Jian Luo	MGC020325	6441

7590 10/02/2007

Jian Luo
240 Klamath Street
Brisbane, CA 94005

EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,382	LUO ET AL.	
	Examiner	Art Unit	
	Paul W. Dickinson	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *5 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of gemfibrozil and diabetes mellitus in the reply filed on 8/22/2007 is acknowledged. The traversal is on the ground(s) that all lipid-improving agents selected from non-glucose-lowering fibrates have the same special technical feature because:

1. A "lipid-lowering agent" is restricted by "non-glucose-lowering fibrates"

2. Fibrates are commonly known as a class of drug that reduces plasma triglycertides and increases plasma HDL cholesterol. They all belong to a chemical structure class called "fibrate" and possess the same pharmacological mechanism of action by acting on PPARalpha receptors.

3. "Non-glucose-lowering" should be considered a common special technical feature for the fibrates claimed in the instant application.

Furthermore, the disclosed diseases, disorders or conditions relate to a single general inventive concept because:

1. The disclosed species all have a component of "abnormality in plasma glucose levels or glucose metabolism" and the "abnormality in plasma glucose levels or glucose metabolism" is the same or corresponding special technical feature.

This is not found persuasive for the following reasons. It is accepted that "non-glucose-lowering fibrates" restricts "lipid-lowering agents." It is further accepted that fibrates belong to the same class of compounds and each species of fibrate has

overlapping pharmacological mechanisms with another. This notwithstanding, each fibrate indeed has a different molecular structure and a different bioactivity. Selection of a given fibrate for administration to a patient in need thereof is dependent on the patient and each fibrate requires a different dosage regime and consideration of side effects. It is further accepted that each of the listed diseases, disorders or conditions all have a component of "abnormality in plasma glucose levels or glucose metabolism". This notwithstanding, each of the listed diseases, disorders or conditions have different causes, symptoms and each requires a different treatment regime. For example, treatment of obesity commonly encompasses an energy-limited diet and increased exercise. Treatment of, say, pancreatitis, does not commonly encompass these steps.

The election requirement is still deemed proper and is therefore made FINAL. Applicant is reminded that the purpose of the election requirement is to begin prosecution on the merits. Upon allowance of the elected species, Applicant will be entitled to consideration of the non-elected species.

Claims 1-4, 7-10 are encompassed by the elected species and are currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The range limitation in claim 4 is vague and indefinite. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation 1:0.1 to 1:10, and the claim also recites 1:0.5 to 1:2" which is the narrower statement of the range/limitation.

The phrase "administered... at about the same time" in claim 8 is vague and indefinite. The term "about" in the above phrase is not defined by the claim and it is unclear what time difference "about the same time" encompasses. Lacking further clarification, "at about the same time" could reasonably encompass a time difference of

minutes, hours, or days. One skilled in the art would not reasonably know if administration of the first component followed by subsequent administration of the second component, wherein the time difference between each administration were, say, several days, would constitute infringement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Paterniti et al (WO9805331). Paterniti et al discloses a pharmaceutical composition comprising metformin, a PPARalpha agonist, and a pharmaceutically acceptable carrier (see p 13, ln 19-29). It is known in the art that PPARalpha agonists are lipid-improving agents (see Marrapodi et al, Peroxisome Proliferator-Activated Receptor alpha (PPARalpha) and Agonist Inhibit Cholesterol 7alpha-Hydroxylase Gene (CYP7A1) Transcription, Journal of Lipid Research, 41, 2000, 514-520; see abstract). Although Paterniti et al discloses gemfibrozil only as a preferred PPARalpha agonist, the group of preferred compounds from which this compound is selected contains only five compounds (see abstract; p 8 ln 28 to p 9 ln 1). A genus may be so small that, when considered in light of the totality of the circumstances, it would anticipate the claimed

species or subgenus. For example, it has been held that a prior art genus containing only twenty compounds and a limited number of variations in the generic chemical formula inherently anticipated a claimed species within the genus because "one skilled in [the] art would... envisage each member " of the genus. In re Petering, 301 F.2d 676, 681, 133 USPQ 275, 280 (CCPA 1962) (emphasis in original).

It is noted that the pharmaceutical composition disclosed by Paterniti et al contains additional components. Applicant is reminded that the transitional term "comprising" in Instant Claim 1, which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements.

Paterniti et al further discloses a method for treating diabetes mellitus (also known as type 2 diabetes) by administration of the above composition to a mammal (see p 1, ln 1-2; p 5, ln 11-20) by oral administration (p 13, ln 15-16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paterniti et al (see above).

Paterniti et al discloses a pharmaceutical composition comprising metformin, a PPARalpha agonist, and a pharmaceutically acceptable carrier (see above). Paterniti et al discloses gemfibrozil as a preferred PPARalpha agonist (see above). Paterniti et al fails to disclose a composition wherein the weight ratio of metformin and gemfibrozil ranges from 1:0.1 to 1:10.

Paterniti et al discloses, however, that it is well within the capability of those skilled in the art, especially in light of the detailed disclosure, to determine effective amounts (p 39, 14-17) and that the exact formulation can be chosen by the individual physician in view of the patient's condition (see p 37, ln 6-8). Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barelli et al (US 5922769) in view of Ko et al (Ko et al, Comparison of the Effects of Gemfibrozil (600 MG Twice Daily and 900 MG Once Daily) on Lipid and Glucose Levels in Chinese Patients with Non-Insulin-Dependent Diabetes Mellitus, Current Therapuetic Research, 56 (10), 1995, 1033-1040).

Barelli et al discloses administration of a pharmaceutical composition comprising metformin for the treatment of diabetes mellitus (see col 3, ln 13-18; Claims 1-7). Barelli

et al fails to disclose administration of a pharmaceutical composition comprising gemfibrozil.

Ko et al discloses administration of a pharmaceutical composition comprising gemfibrozil for the treatment of diabetes mellitus (see abstract).

One skilled in the art would be motivated to combine the teachings of Barelli et al and Ko et al to treat diabetes mellitus. Specifically, one would be motivated to administer a pharmaceutical composition comprising metformin and separately a pharmaceutical composition comprising gemfibrozil at about the same time. It is noted above that "administration... at about the same time" in Claim 8 is vague and indefinite.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul W Dickinson
Examiner
Art Unit 1609

September 24, 2007

CECILIA TSANG
SUPERVISORY PATENT EXAMINER